REMARKS

Claims 87-147 are pending. No new matter has been added by way of the present submission. For instance, the specification has been amended to correct some minor and inadvertent typographical errors. Further, claim 138 has been amended in accordance with the Examiner's suggestion. Additionally, claims 140-147 are newly added. Claims 140 and 141 are based on the specification, please see from page 29, line 26 to page 30, line 16. Further, claim 142 and 144 are based on page 33, line 15-17 of the specification. Claim 143 is based on original claim 77 (in the PCT publication). Claim 145 and 147 are based on previous claim 138. Lastly, claim 146 is based on the following parts of the specification: page 38, lines 20-21, page 39, lines 24-29, page 40, lines 20-23 and page 27, lines 14-15. Thus, no new matter has been added.

In view of the following remarks, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims.

Objection to the Specification

The Examiner has objected to the disclosure due to typographical errors. Applicants respectfully traverse and submit that the errors noted by the Examiner, among others, have been corrected. Thus, this objection is moot.

Issue under 35 U.S.C. § 112, second paragraph

Claim 138 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection and submit that claim 38 has been

amended as suggested by the Examiner. Thus, it is respectfully requested that this rejection be withdrawn.

Issues under 35 U.S.C. §§ 102(b)/102(e)/103(a)

Claims 132-139 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 7,265,084, DeFrees et al., (hereinafter referred to as DeFrees' 084).

Further, claims 132-139 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bülter (hereinafter referred to as Bülter) in view of DeFrees '084.

Claims 132-136 and 138 remain rejected and new claim 139 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bülter.

Finally, claims 132, 134, 135 and 138 remain rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication 2004/0253651, Saarinen et al. (hereinafter referred to as Saarineen).

Applicants respectfully traverse these rejections.

The Present Invention is Distinct from Bülter

Applicants note in the previous reply that Bülter describes 6-modified monosaccharide residues, while present invention is directed to chemically very distinct 2-modified monosaccharide residues. The Examiner responded that "for rejection to constitute anticipation, all material elements of a claim must be found in the cited reference" and the Examiner does not find the Applicants' arguments persuasive because (on page 13, paragraph 7, 2 last lines at the end of page to beginning of next page) Bülter does teach a 2-modified monosaccharide. "Scheme 1 teaches R groups attached to position 2 of the galactose monosaccharide in UDP-Gal or

UDP-GalNAc, which would be a modification of the monosaccharide".

Applicants respectfully submit that although the teaching of Bülter may appear to be as suggested by the Examiner, in fact, on closer examination of the "Scheme", it reveals that the R groups in Bülter does not represent any modification of the position 2 of the galactose monosaccharide in UDP-Gal or UDPGalNAc. In contrast, the two R groups simply present the two alternative monosaccharide residues Gal (when R is OH, in substances 1, 3, 5, and 7) and GalNAc (when R is NHAc, in substances 2, 4, 6 and 8). As a reference, Applicants direct the Examiner's attention to monosaccharide structures from "Essentials of Glycobiology" as provided (see the Figure below). Therefore, Bülter does not represent any 2-position modified monosaccharides. There is further no reason to modify the disclosure of Bülter to arrive at the present invention. In the Figure, structures of galactose (first row, 2nd from right OH on position 2) and GalNAc (first row 1st on right, HNAc on position 2) are represented in Essentials of Glycobiology, see http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=glyco2.

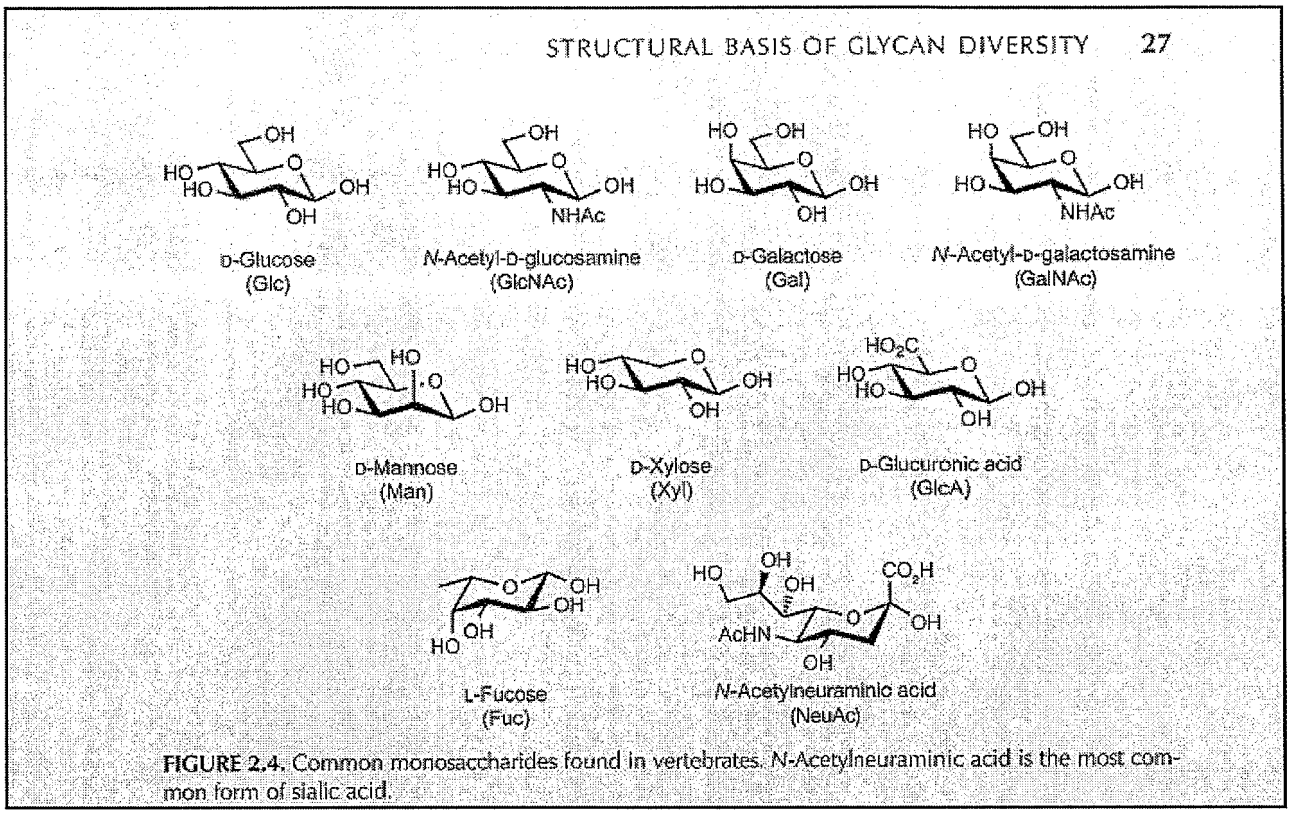


FIGURE 2.4. Common monosaccharides found in vertebrates. N-Acetylneuraminic acid is the most common form of sialic acid.

The Present Invention is Distinct from Saarinen

Applicants previously argued that galactosamine GalN is a monosaccharide. The Examiner is of the opinion that UDP-GalN would be galactose modified by the addition of N and UDP. It is notable that galactosamine or glucosamine, though could be considered as a modification of corresponding hexoses as any other monosaccharide can be considered as a derivative of any other monosaccharide, are aminodeoxysugars/monosaccharides, see IUPAC Carbohydrate nomenclature *Eur. J. Biochem.*, 126, 433-437, page 434, first column, line 22, paragraph g) and Example I, second column, page 434. The fact that galactosamine is a monosaccharide is also obvious from the Examiner's analysis of DeFrees in the Office Action,

see page 4, last paragraph, line 3 from below "monosaccharide (galactose, glucose, mannose, galactosamine or glucosamine)".

The Present Invention is Distinct from DeFrees '084

(a) Nucleotide sugars

DeFrees '084 lists all theoretically possible substitution derivatives of all natural nucleotide sugars. There is no experimental evidence of these molecules except CMP-sialic acid derivatives very analogous already known in the prior art (referred by Miller). The invention of DeFrees '084 appears not to have been brought to practice with regard to the 2-modified monosaccharide residues (or other monosaccharide derivatives except specific sialic acid derivatives).

Based on Bülter, the synthesis of modified nucleotide sugars is not trivial task and may fail unexpectedly. Bülter managed to produce its molecule effectively after several serious problems in many steps, such as inactivation of the galactose oxidase enzyme (page 887 lines 4-6), and needing to include unusual step by frozen solid phase synthesis in - 20 deg Celsius (Figure 2).

(b) Monosaccharides modified by a reactive group

The present invention revealed 2-modified monosaccharides with reactive linking group. New claim 140 is directed to this specific embodiment. Such were not disclosed by DeFrees '084.

(c) Reactions to cells or tissues

There is no evidence of reactions to cells or tissues in DeFrees '084. It is known that glycans on cell or tissue surfaces can be cryptic and not accessible for enzymes. Furthermore, the enzyme specific for the specific glycoconjugate available on the cell or tissue surface and additionally capable of transferring the modified monosaccharide would be needed (e.g. Bülter demonstrated substrate specificities of enzymes). Also, alteration of the donor structure may affect the acceptor specificity. The present invention was first to demonstrate reactions with cells/tissues and 2-modifed monosaccharide residues. New claims directed to cells and tissues have been added (claims 142 and 144).

(d) Enzymes

DeFrees '084 does not provide experimental evidence of an enzyme effectively transferring 2-modified galactose/galactosamine. Apparently this embodiment was not brought to practice. It would be evident to a skilled person that endless screening processes would have been needed to get suggested molecules to work with transferase based on very broad description of DeFrees '084.

The Present Invention cannot be achieved by a combination of Bülter and DeFrees '084

Bülter is only relevant with regard to 6-modified Gal(NAc) and transfer thereof. It cannot be combined to 2-modified monosaccharide speculation of DeFrees '084. Therefore, a skilled professional could not have combined DeFrees '084 with Bülter.

DeFrees '084 provides a suggestion of transferring monosaccharide derivative by bovine milk betal-4-galactosyltransferase (apparently only galactosyltransferase named in DeFrees '084,

see paragraph [0832]). Bülter shows that this enzyme is especially bad choice even inactive (page 888, column 1, 1st paragraph, lines 5-11) for the 6-modifed galactose derivatives, so the teaching of DeFrees '084 is towards inactive regular transferase variants and not to engineered transferase as shown by the present invention. DeFrees '084 does not show that this embodiment or any other hexose derivative would have been brought to practice (see paragraph [1643] and [1565]) DeFrees '084 actually refers to transfers of UDP-Gal-6PEG which are similar to the ones in Bulter with Ga1T1 (Bovine milk GalT is Ga1T1). No reference to 2-PEG modified Gal(N) was found from Defrees, see paragraphs 1334 and 1336 describing synthesis of 6-modified GalNAc and G1cNAc.

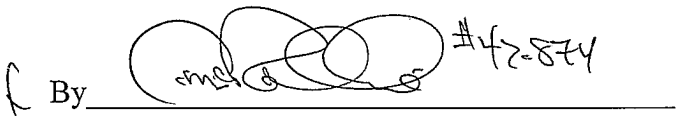
In view of the above, Applicants believe that the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie, Reg. No. 42,874, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: December 14, 2009

Respectfully submitted,



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Eur. J. Biochem. *126*, 433–437 (1982)

IUPAC-IUB Joint Commission on Biochemical Nomenclature (JCBN)

Abbreviated Terminology of Oligosaccharide Chains

Recommendations 1980

CONTENTS

Systematic names and structural formulas of oligosaccharides and of oligosaccharide chains in polysaccharides and in glycoconjugates become unwieldy with increasing molecular size, and for large molecules there is a need for an abbreviated terminology. The recommendations below, based upon a report by a subcommittee,* follow in the main what has become established practice in the carbohydrate literature.

In the recommendations given herein, which are, as far as possible, formulated within the framework of the IUPAC-IUB Tentative Rules for Carbohydrate Nomenclature (1), all available structural information is given explicitly. When a more condensed set of abbreviations is desired, the recommendations given in Section Lip-3 of the Nomenclature of Lipids (2) should be used. These recommendations, with some examples of their application, are given in the "Appendix" to the present document.

DEFINITIONS

An oligosaccharide is a molecule containing a small number (2 to about 10) of monosaccharide residues, connected by glycosidic linkages. A carbohydrate containing two such residues is a disaccharide, a carbohydrate containing three such residues is a trisaccharide, and so on.

Document of the IUB-IUPAC Joint Commission on Biochemical Nomenclature (JCBN) whose members are P. Karlson (Chairman), H. B. F. Dixon, Y. Jeannin, C. Liébecq (as Chairman of the IUB Committee of Editors of Biochemical Journals), B. Lindberg, K. L. Loening, G. P. Moss, and S. F. Velick in consultation with J. F. G. Vliegenthart and the Nomenclature Committee of IUB, whose additional members are H. Bielka, W. B. Jakoby, B. Keil, and E. C. Webb. Comments or suggestions for modifications may be sent to the secretary of JCBN, H. B. F. Dixon, Department of Biochemistry, Tennis Court Road, Cambridge, United Kingdom CB2 1QW, or to any member. JCBN thanks the expert subcommittee of B. Lindberg (convener), D. Horton, the late W. Klyne, K. L. Loening, D. J. Manners, W. G. Overend, H. Paulsen, D. A. Rees, and R. S. Tipson for drafting these proposals.

RECOMMENDATIONS

1. Trivial Names

(*a*) Certain trivial names firmly established in the literature are specific for particular structures, and their continued use is allowed in instances where the full name may be unwieldy.

Examples: *Disaccharides:* Cellobiose, chitobiose, gentiobiose, kojibiose, lactose, melibiose, sophorose, sucrose, α,α-trehalose, turanose.
Tri- and Oligosaccharides: Melezitose, panose, raffinose, stachyose.

Further examples are given in Section Lip-3 of the Nomenclature of Lipids (2).

(*b*) Such disaccharide names as xylobiose and mannobiose, which are ambiguous, should only be used when there is no risk of confusion. The systematic name should be given together with the trivial name, at the first mention.

(*c*) The accepted trivial names for disaccharides should only be extended to higher oligosaccharides when the latter contain a single type of sugar residue and linkage.

Examples: Cellotetraose, maltotriose.

When, however, the trivial name is derived from the name of a carbohydrate that contains two or more different sugars, or types of linkage, or both, extension of the names to higher oligosaccharides is *not* recommended.

Examples: *Not* recommended are such names as agarotetraose and nigerotriose.

2. Systematic Names

These should be assigned as indicated in Carb-39 and Carb-40 (1).

3. Abbreviated Names for Use for Oligosaccharides

(*a*) The symbols chosen are derived from the trivial names of the constituent sugars. For the sake of clarity, brevity, and listing in tables, the symbols have, wherever possible, been restricted to three letters, usually the first three letters of the trivial name.

Allose	= All	Arabinose	= Ara	Rhamnose	= Rha
Altrose	= Alt	Lyxose	= Lyx	Fucose	= Fuc
Galactose	= Gal	Ribose	= Rib		
Glucose	= Glc	Xylose	= Xyl	Fructose	= Fru
Gulose	= Gul			Neuraminic acid	= Neu
Idose	= Ido			Muramic acid	= Mur
Mannose	= Man				
Talose	= Tal				

Symbols derived from less common trivial names may be used, but the systematic name should be given together with the trivial name and the abbreviation at the first mention.

Examples: 3,6-Dideoxy-D-*xylo*-hexose (abequose = Abe)
6-Deoxy-D-glucose (quinovose = Qui)
3-C-(Hydroxymethyl)-D-*glycero*-aldotetrose (D-apiose = Api)

(*b*) The symbols represent the structural formulas of the compounds and also their names.

(*c*) The symbols represent the individual sugars or their residues. The use of the symbol to represent the free sugar is not recommended in textual material, but such use may occasionally be desirable in tables, diagrams and figures.

(*d*) The ring form is indicated, where necessary, by using the first letter of furanose, pyranose, or septanose, italicized and uncapitalized, added after the abbreviated name of the monosaccharide.

Examples: Arabinofuranose = Ara*f*
Glucopyranose = Glc*p*

(*e*) *Uronic Acid*—The suffix A is added to the symbol for the parent monosaccharide.

Examples: Glucuronic acid = GlcA
Galactopyranuronic acid = Gal*p*A

(*f*) *Deoxy Sugars*—Rational names, but no abbreviations, are recommended. One exception is 2-deoxy-D-*erythro*-pentose (deoxyribose) which is abbreviated dRib.

(*g*) *Aminodeoxy Sugars*—For 2-amino-2-deoxy sugars, the suffix N is added to the symbol of the parent monosaccharide. If the latter is *N*-acetylated, the suffix becomes NAc.

Examples: 2-Amino-2-deoxy-D-glucopyranose = D-Glc*p*N
2-Amino-2,6-dideoxy-L-galactose = L-FucN
2-Acetamido-2-deoxy-D-mannopyranose = D-Man*p*NAc

For other, less common, aminodeoxy sugars, the appropriate locants are added before N.

Example: 3,6-Bis(acetamido)-3,6-dideoxymannose = Man3,6$(NAc)_2$

(*h*) For anhydro sugars, the appropriate locants and the prefix An are added before the symbol of the parent monosaccharide.

Example: 3,6-Anhydrogalactose = 3,6AnGal

(*i*) *Configuration*—The configurational symbol (D or L) is included before the symbol for the monosaccharide, and is separated therefrom by a hyphen.

Examples: D-Glucopyranose = D-Glc*p*
L-Arabinofuranose = L-Ara*f*
3,6-Anhydro-D-galactose = 3,6An-D-Gal

(*j*) *Anomeric Configuration*—The anomeric symbol (α or β) is included before the configurational symbol and separated therefrom by a hyphen.

Examples: α-D-Glucopyranose = α-D-Glc*p*
β-L-Arabinofuranose = β-L-Ara*f*

(*k*) Structural formulas may be used for complicated features together with the abbreviated notation whenever necessary for clarity.

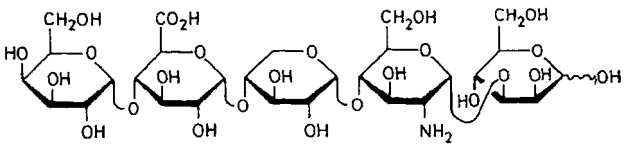
4. *Unbranched Oligosaccharides*

Between the symbol (abbreviated name) of one monosaccharide group or residue and the next are placed two locants that indicate the respective positions involved in this glycosidic union. These locants are separated by an *arrow* (directed from the locant corresponding to the glycosyl carbon atom to the locant corresponding to the carbon atom carrying the hydroxyl group involved) and are enclosed in parentheses (see Rule Carb-40 (1)). For nonreducing oligosaccharides, *double-headed arrows* are used between the locants of the appropriate glycosyl carbon atoms when the symbols are used, but not when the names are spelled out.

The hyphens, except that separating the configurational symbol and the symbol for the monosaccharide, may be omitted, *e.g.*

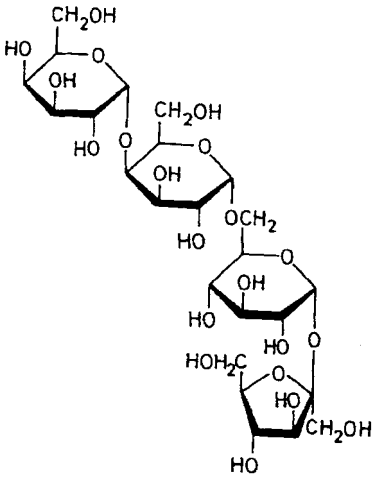
αD-Gal*p*(1 → 4)αD-Glc*p*A(1 → 4)αD-Xyl*p*(1 → 4)αD-Glc*p*N(1 → 3)D-Man

Examples:



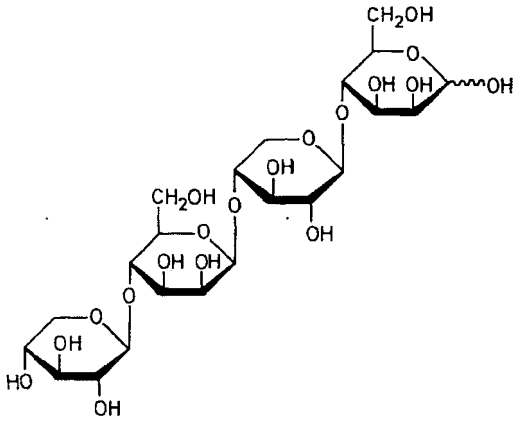
α-D-Gal*p*-(1 → 4)-α-D-Glc*p*A-(1 → 4)-α-D-Xyl*p*-(1 → 4)-α-D-Glc*p*N-(1 → 3)-D-Man*p*

I



α-D-Gal*p*-(1 → 4)-α-D-Gal*p*-(1 → 6)-α-D-Glc*p*-(1 ↔ 2)-β-D-Fru*f*

II



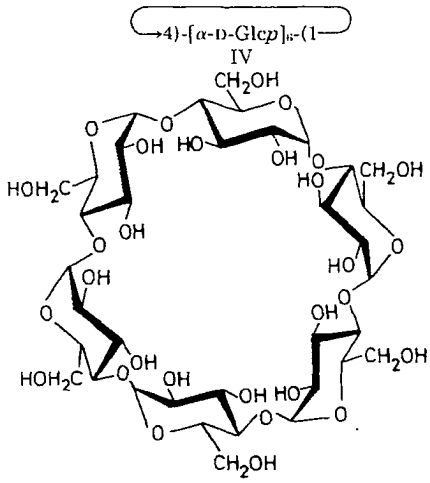
β-D-Xyl*p*(1 → 4)-β-D-Man*p*-(1 → 4)-β-D-Xyl*p*-(1 → 4)-D-Man*p*

III

5. *Cyclic Oligosaccharides*

A cyclic oligosaccharide is symbolized as illustrated below.

Example: Cyclomaltohexaose (the older names cyclohexaamylose, Schardinger α-dextrin or α-cyclodextrin, are not recommended).



IV

6. *Branched and Substituted Oligosaccharides*

(*a*) Substituents may be symbolized as follows:

acetyl	= Ac	methyl	= Me
benzoyl	= Bz	phenyl	= Ph
benzyl	= Bzl, $PhCH_2$ (Bn)	*p*-toluenesulfonyl tosyl	= Tos (Ts)
ethyl	= Et		
glycolyl	= Gl	trimethylsilyl	= Me_3Si
methanesulfonyl mesyl	= $MeSO_2$ (Ms)	trityl	= Trt, Ph_3C (Tr)

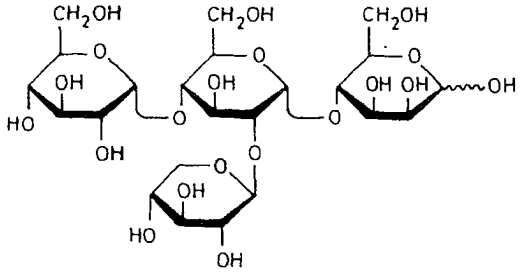
Most of these symbols are in the lists of those recommended for biochemical use (3) or for symbolizing derivatives of amino acids (4). Some symbols that are commonly used in the carbohydrate literature are given in parentheses. Substituents will not carry prefixes if attached to oxygen or nitrogen, but will be preceded by an italicized *C* if attached to carbon. The position of the substituent will be shown by the appropriate numeral. Substituents directly follow the abbreviation for the monosaccharide residue.

Examples:

Ethyl D-glucopyranuronate	= D-Glc*p*A6Et
β-D-Galactopyranose 4-sulfate	= β-D-Gal*p*4SO_3
2-*C*-Methyl-D-xylose	= D-Xyl2*C*Me
3,4-Di-*O*-methyl-L-rhamnose	= L-Rha3,4Me_2
N-Acetylneuraminic acid	= Neu5Ac
N-Acetyl-2-deoxyneur-2-enaminic acid	= Neu2en5Ac

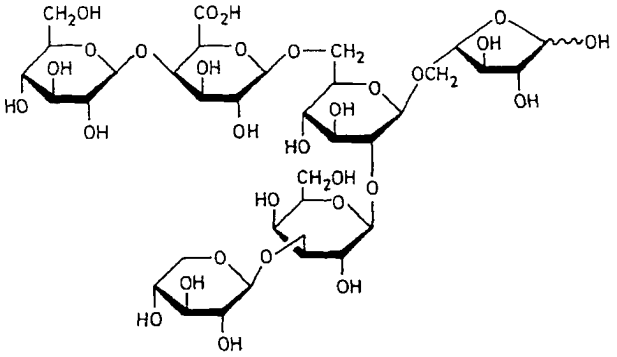
(*b*) For branched oligosaccharides, the main chain and oligosaccharide side chains will be depicted as outlined for unbranched oligosaccharides. The position of a branch is indicated above, or below, the main chain, with the numerals and an *arrow* indicating the glycosidic linkage.

Examples:



α-D-Glc*p*-(1 → 4)-α-D-Glc*p*-(1 → 4)-D-Man*p*
2
↑
1
β-D-Xyl*p*

V

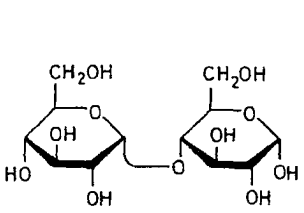


β-D-Glc*p*-(1 → 4)-β-D-Gal*p*A-(1 → 6)-β-D-Glc*p*-(1 → 5)-L-Ara*f*
2
↑
1
β-D-Xyl*p*-(1 → 3)-β-D-Gal*p*

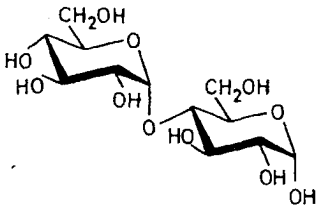
VI

(*c*) In drawing structural formulas, Haworth perspective formulas (formula 1), conformational formulas (formula 2) or Mills (5) formulas (formula 3) may be used (1, 6). It should be borne in mind that the detailed conformation indicated by a conformational formula has not always been established. Mills formulas are particularly useful in describing synthetic work. Use of a Fischer projection (formula 4) is sometimes advisable.

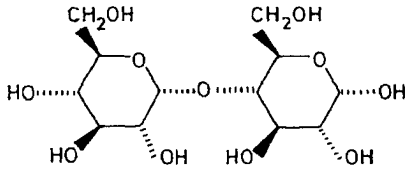
Examples:



Formula 1

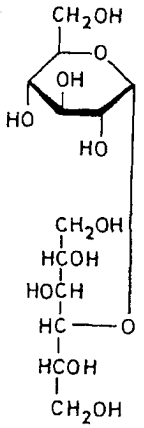


Formula 2



Formula 3

α-Maltose



Maltitol, 4-*O*-α-D-glucopyranosyl-D-glucitol

Formula 4

Appendix

The Condensed System of Symbolism of Sugar Residues in Oligosaccharides and Oligosaccharide Chains

In the condensed system the common configuration and ring size are implied in the symbol. Thus, Glc means D-glucopyranose; Fru, D-fructofuranose; and Fuc, L-fucopyranose. Whenever the configuration or ring size is found to differ from the common one, or is to be emphasized, this may be indicated by using the appropriate symbols from the extended system.

The anomeric descriptor indicates the configuration of the glycoside linkage, and is therefore placed before the locant if the direction of the bond is to the right, or after the locant if the direction of the bond is to the left. The two locants are separated by a hyphen. No hyphens are used between the symbol for the sugar and the parentheses indicating the glycosidic bond.

Example: Raffinose = Gal(α1-6)Glc(α1-2β)Fru

The parentheses may be omitted in representing branched oligosaccharides, when parentheses are used to indicate the branches. In this way it is possible to write branched sequences on one line, as shown in the examples.

Comment—The main difference between the extended form and the condensed form is the place of the anomeric descriptor, α or β. In the extended form the anomeric descriptor is considered to be part of the name (symbol) of the sugar unit; this system is preferred by carbohydrate chemists. In the condensed system the anomeric descriptor specifies the type of glycosidic linkage. This usage, first codified in *Abbreviations and Symbols for Chemical Names of Special Interest in Biological Chemistry* (7), is preferred by many biochemists. JCBN has been unable to reach a consensus as to which system should be recommended for general use, so gives both systems here as optional.

As in the extended system, placing a hyphen or parenthesis to the right of the symbol for a monosaccharide residue signifies removal of OH from the reducing carbon. Thus amygdalin may be represented:

Extended: β-D-Glc*p*-(1 → 6)-β-D-Glc*p*-O-CH(CN)-Ph
Condensed: Glc(β1-6)Glc(β)-O-CH(CN)Ph

This also applies in representing glycolipids (Ref. 2, Section Lip-3).

The following examples illustrate the use of the two different systems. They refer to the numbered structural formulas given above.

Comment—For long or multiple branches it may be advisable to use the two-line notation even in the condensed system.

Structure I

Extended: α-D-Gal*p*-(1 → 4)-α-D-Glc*p*A-(1 → 4)-α-D-Xyl*p*-(1 → 4)-α-D-Glc*p*N-(1 → 3)-D-Man*p*
Condensed: Gal(α1-4)GlcA(α1-4)Xyl(α1-4)GlcN(α1-3)Man

Structure II

Extended: α-D-Gal*p*-(1 → 4)-α-D-Gal*p*-(1 → 6)-α-D-Glc*p*-(1 ↔ 2)-β-D-Fru*f*
Condensed: Gal(α1-4)Gal(α1-6)Glc(α1-2β)Fru

Structure III

Extended: β-D-Xyl*p*-(1 → 4)-β-D-Man*p*-(1 → 4)-β-D-Xyl*p*-(1 → 4)-D-Man*p*
Condensed: Xyl*p*(β1-4)Man(β1-4)Xyl*p*(β1-4)Man

Note—In this case Xyl*p* is used in the condensed system to stress the pyranose form.

Structure IV

Extended: →4)-[α-D-Glc*p*]$_n$-(1
Condensed: [→4Glcα1→]$_n$ or [4Glcα1]$_n$

Structure V

Extended: α-D-Glc*p*-(1 → 4)-α-D-Glc*p*-(1 → 4)-D-Man*p*
2
↑
1
β-D-Xyl*p*
Condensed: Glcα1-4(Xylβ1-2)Glcα1-4Man

Structure VI

Extended: β-D-Glc*p*-(1 → 4)-β-D-Gal*p*A-(1 → 6)-β-D-Glc*p*-(1 → 5)-L-Ara*f*
2
↑
1
β-D-Xyl*p*-(1 → 3)-β-D-Gal*p*
Condensed: Glcβ1-4GalAβ1-6(Xylβ1-3Galβ1-2)Glcβ1-5Ara
or
Glcβ1-4GalAβ1-6Glcβ1-5Ara
2
↑
Xylβ1-3Galβ1

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Acknowledgement. We are indebted to the American Society of Biological Chemists for permission to reproduce this document which appeared earlier in the *J. Biol. Chem. 257,* 3347–3351 (1982).